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Gender Differences in Anxiety and Concerns about the Cardioverter Defibrillator

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Background: *Little is known about gender differences in the response to implantable cardioverter defibrillator (ICD) therapy. We compared female and male ICD patients on anxiety, depression, health-related quality of life (HRQL), ICD concerns, and ICD acceptance.*

Methods: *A cohort of consecutive, surviving patients (n = 535; mean age = 61.5 ± 14.4, 81.9% male) implanted with an ICD between 1989 and 2006 completed the Hospital Anxiety and Depression Scale, the Short-Form Health Survey (SF-36), the ICD concerns questionnaire, and the Florida Patient Acceptance Survey.*

Results: *High levels of anxiety (52% vs 34%, P < 0.001) and ICD concerns (34% vs 16%, P = 0.001) were more prevalent in women than men, whereas no significant differences were found on depression and device acceptance (Ps > 0.05). Women were more anxious (odds ratio [OR]: 2.60 [95% confidence interval (CI): 1.46–4.64], P < 0.01) and had more ICD concerns (OR: 1.81 [95% CI: 1.09–3.00], P < 0.05) than men, adjusting for demographic and clinical characteristics. Those ICD patients experiencing shocks were also more anxious (OR: 2.02 [95% CI: 1.20–3.42], P < 0.01) and had higher levels of ICD concerns (OR: 2.70 [95% CI: 1.76–4.16], P < 0.01). In multivariable analysis of variance, significant gender differences were found for only three of the eight subscales of the SF-36 (the physical social functioning and the mental health subscale), with women reporting poorer HRQL on all three subscales.*

Conclusions: *Women were more prone to experience anxiety and ICD concerns compared to men regardless of whether they had experienced shocks. In clinical practice, female ICD patients should be closely monitored, and if warranted offered psychosocial intervention, as increased anxiety has been shown to precipitate arrhythmic events in defibrillator patients. (PACE 2009; 32:614–621)*

cardioverter defibrillator, gender, anxiety, ICD concerns

Introduction

The medical benefits of implantable cardioverter defibrillator (ICD) therapy are well established.[1–3] Nevertheless, there is a considerable gap in the implantation rate of the ICD between women and men, with women being less likely to receive an ICD.[4–7] Although gender differences in cardiac electrophysiology and arrhythmias have been identified,[8] the survival benefits of ICD therapy are similar in men and women.[4,9] The reasons for the disparity in implantation rates are largely unknown,[10] with differences in age, patient preferences (e.g., refusal rates), and comorbid conditions between men and women being unlikely explanations.[4]

ICD implantation and therapy may be associated with both medical and psychological complications,[2,11] including increased anxiety, depression, avoidance behaviors, and impaired health-related quality of life (HRQL),[12] although only a subgroup of patients tend to experience difficulties following implantation.[12] Since women generally are more likely to be anxious, depressed, and to report poorer HRQL compared to men,[13,14] female ICD patients may also be at higher risk of these outcomes than male patients.

Paradoxically, little is known about gender differences in these patient-centered outcomes in patients treated with ICD therapy, with available studies being based on a relatively small number of women. Two studies found no gender differences in anxiety and depression,[15,16] whereas a third study found female gender and shocks to be associated with both anxiety and depression.[17] In relation to HRQL, one study found that women report lower functional status compared to men.[16] Another study showed women to have lower scores on the SF-36 role emotional functioning subscale at 3 months postimplant compared to men, but this difference was no longer significant at 12 months.[18] In contrast, women consistently reported better general health as compared to men.[18]

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The aims of the current study were to examine (1) whether women are at a greater risk of increased anxiety, depression, ICD concerns, and lower device acceptance, and (2) whether women have poorer HRQL compared to men, adjusting for demographic and clinical characteristics.

Method

Patients and Study Design

ICD patients implanted with an ICD at Aarhus University Hospital (Skejby), Denmark, since 1989 and still alive on November 1, 2006, were included in the current study. ICD patients implanted with a first ICD within the last 3 months were excluded. Generally, prophylactic implantation was not implemented in Denmark prior to 2007; therefore, the majority of patients (94.8%) had a secondary indication for ICD. The design of the study has been previously published.[19] Of 723 eligible patients, 624 (86%) participated.[19] Cases without any scores on individual items of the psychological scales used in the current study were excluded from statistical analysis (n = 75). For the remaining cases, missing data were imputed using the expectation-maximization (EM) algorithm, which has been demonstrated to be an effective method of dealing with missing data.[20] Hence, for the current study analyses were based on 535 patients (81.9% male; mean age = 61.5 ± 14.4 years; mean time since first ICD implantation = 4.6 ± 3.2 years).

All surviving ICD patients received information about the study by mail and were asked to complete a self-report questionnaire containing questions on clinical data and standardized and validated psychological questionnaires. Reminders, including a duplicate of the questionnaire, were mailed to nonresponders after 2 weeks. The study was conducted in accordance with the Helsinki Declaration.

Measures

Demographic and Clinical Variables

Demographic variables comprised gender, age, and having a partner. Clinical variables included etiology of heart disease (i.e., ischemic vs nonischemic, with nonischemic defined as cardiomyopathy [hypertrophic, dilated, other], idiopathic ventricular fibrillation, arrythmogenic right ventricular, congenital heart disease, congenital long QT, valvular heart disease, or Brugada syndrome), symptomatic heart failure (HF), comorbidity, device-related complications, time since first implantation, and having experienced shocks (shocks ≥1). Information on clinical variables was retrieved from the patients' medical records, the Danish ICD Registry,[21] and from purpose-designed questions. All reoperations caused by device or lead malfunctioning or infection, as registered by the Danish ICD Registry,[21] were considered as complication to ICD therapy. Comorbidity (e.g., gait, diabetes, muscular dystrophy, stroke, cancer, pulmonary disease, and renal insufficiency) and number of ICD shocks were based on self-report. Symptomatic HF was determined using the Minnesota Living with Heart Failure (MLHF) questionnaire.[22] The 21-item MLHF is a valid and reliable, disease-specific measure of HRQL, with items scored on a six-point Likert scale from 0 (no) to 5 (very much). The total MLHF score ranges from 0 to 105, with a lower score indicating good HRQL. Dichotomization was undertaken in order to enhance the interpretation of the results in clinical practice.[23] A MLHF score above 40 represents New York Heart Association (NYHA) classes III and IV (i.e., symptomatic HF).[24] The 75% upper percentile in our data was 41 corresponding with NYHA classes III and IV, and the cutoff of >40 on the MLHF was used as a marker of symptomatic HF.

Hospital Anxiety and Depression Scale©

The HADS© is a 14-item self-report measure, consisting of two 7-item subscales measuring anxiety and depressive symptoms.[25] Responses are indicated on a four-point Likert Scale from 0 to 3 (score range 0–21). The two subscales have been shown to be internally consistent, as measured by Cronbach's α: HADS-A = 0.80; HADS-D = 0.81.[26] In addition, a recent review of 15 studies showed HADS to be a valid and reliable instrument, with Cronbach's α for HADS-A ranging from 0.68 to 0.93 and for HADS-D ranging from 0.67 to 0.90.[27] This review also showed ≥8 on both subscales to be an optimal cutoff point as an indication of likely psychopathology, with sensitivity and specificity ranging between 0.70 and 0.90 for most reviewed studies.[27] In the current study, this cutoff was used to dichotomize symptoms into present or nonpresent to obtain the best clinical indication of anxiety or depressive symptoms. The HADS has been used in both cardiac and noncardiac populations, and is appropriate to use in patients with somatic disease, as it is devoid of somatic symptoms.[27]

ICD Concerns

Device-related concerns were assessed with the ICD Concerns questionnaire (ICDC). In the current study, we used an adapted and abbreviated

version of the original 20-item questionnaire,[28] the ICDC-8.[29] The internal consistency of the abbreviated version is good ($\alpha = 0.91$),[29] which was confirmed in the current study ($\alpha = 0.94$). The ICDC-8 consists of eight items (i.e., "I am worried about my ICD firing"; "I am worried about having no warning my ICD will fire") rated on a five-point Likert scale from 0 (not at all) to 4 (very much so), with a higher score reflecting a higher level of device-related concerns.

Acceptance of the Cardioverter Defibrillator

The 18-item Florida Patient Acceptance Survey (FPAS) is a disease-specific measure assessing device acceptance.[30] Items are rated on a five-point Likert scale from 0 (strongly disagree) to 5 (strongly agree), with a higher score indicating better acceptance. Only 15 of the 18 items contribute to the four subscales: (1) Return to Function, (2) Device-Related Distress, (3) Positive Appraisal, and (4) Body Image Concerns as well as the total score.[30] The convergent, divergent, and discriminant validity of the FPAS are good, and the scale has been shown to be internally consistent, as indicated by Cronbach's α ranging from 0.74 to 0.83.[30] The validity and reliability of the Danish version of the FPAS has recently been confirmed in the present cohort of ICD patients.[31]

Health-Related Quality of Life

HRQL was assessed with the 36-item Short-Form Health Survey (SF-36), which is a generic measure of HRQL.[32,33] The SF-36 consists of 36 items grouped into eight subscales: physical functioning, role physical functioning (measures the impact of physical health on work or other daily activities), role emotional functioning (measures the impact of emotional problems on work or other daily activities), mental health, vitality, social functioning, bodily pain, and general health (score range/subscale: 0–100), with higher scores indicating good HRQL or the absence of pain. The SF-36 has proven to be a valid and reliable instrument, with Cronbach's α for the various subscales ranging from 0.78 (general health) to 0.93 (physical functioning).[32]

Statistical Analyses

Prior to statistical analyses, scores on the FPAS were dichotomized using the lowest tertile to indicate poor device acceptance (i.e., FPAS $< = 73$).[31] Likewise, scores on the ICDC-8 were dichotomized using the highest tertile to indicate a high level of device-related concerns (i.e., ICDC $> = 74$).[34] Discrete variables were compared using the χ^2 test (Fisher's exact test when appropriate) and continuous variables with Student's *t*-test. Multivariable analysis of variance (MANOVA) was used to examine the influence of gender on HRQL, as measured with the SF-36 subscales. Multivariable logistic regression analyses were used to determine whether gender was independently associated with anxiety, depression, device acceptance, and device-related concerns adjusting for age, partner, time since first implantation, coronary artery disease etiology, symptomatic HF, comorbidity, device-related complications, and one or more shocks ($\geq$1). Based on these results, we conducted two-factor analyses of variance (ANOVA) with gender and shocks as independent variables and anxiety and device-related concerns as the dependent variables. In MANOVA, results for the SF-36 were adjusted for age, partner, time since first implant, coronary artery disease etiology, symptomatic HF, comorbidity, device-related complications, and shocks ($\geq$1). All the covariates entered in adjusted analyses were selected either on the basis of the literature or results of univariable analysis. A P-value of 0.05 was chosen to indicate statistical significance, and all tests were two tailed. Odds ratios (OR) with their corresponding 95% confidence intervals (CI) are reported for the logistic regression analyses. All analyses were performed using SPSS 13.0 for Windows (SPSS Inc., Chicago, IL, USA).

Results

There were no systematic differences (all P-values >0.05) between ICD patients included in the analysis (n = 535) and those excluded (non-responders and responders with incomplete psychological data [n = 194] on gender, age, coronary artery disease etiology, and device-related complications [results not shown]). However, ICD patients included in the study were more likely to have had their ICD for a shorter period of time (4.70 $\pm$ 3.24 vs 5.35 $\pm$ 3.61 years, t = 2.33, P = 0.02).

Patient Characteristics

Patient characteristics for the total group and stratified by gender are displayed in Table I. The total group comprised 438 males and 97 females. Women were younger (55.22 $\pm$ 15.2 vs 62.94 $\pm$ 13.9, P < 0.001) and less likely to have a partner compared to men (66% vs 80%, P = 0.002). In terms of their clinical profile, women were less likely to have ischemic heart disease (37% vs 66%, P < 0.001) but were more likely to suffer from comorbid conditions (35% vs 19%, P < 0.001).

Gender Differences on Anxiety, Depression, Device Concerns, and Acceptance

Descriptive characteristics for each gender and the total group are presented in Table I. ICD

Table I.

Demographic, Clinical, Psychological Characteristics, and Health-Related Quality of Life for the Total Group and Stratified by Gender

	Female (n = 97)	Male (n = 438)	Total (n = 535)	P Value
Demographic				
Age, mean (SD)	55.22 ± 15.2	62.94 ± 13.9	61.54 ± 14.4	**<0.001***
Cohabiting, n (%)	63 (66)	347 (80)	410 (78)	**0.002***
Clinical				
Ischemic etiology, n (%)	36 (37)	291 (66)	327 (61)	**<0.001***
Complications, n (%)	6 (6)	37 (8)	43 (8)	0.458
Symptomatic HF, n (%)	23 (24)	106 (24)	129 (24)	0.919
Shocks, n (%)	40 (41)	185 (43)	225 (43)	0.775
Time since first implant, mean (SD)	4.83 ± 3.2	4.67 ± 3.2	4.70 ± 3.2	0.656
Comorbidity, n (%)	34 (35)	82 (19)	116 (22)	**<0.001***
Psychological				
ICD concerns, mean (SD)	10.34 ± 9.4	6.89 ± 7.7	7.72 ± 8.1	**0.001***
Device acceptance, mean (SD)	77.64 ± 18.0	78.13 ± 16.8	78.04 ± 17.0	0.930
Anxiety, mean (SD)	5.89 ± 4.6	3.92 ± 3.8	4.27 ± 4.0	**<0.001***
Depression, mean (SD)	3.42 ± 3.3	3.22 ± 3.3	3.3 ± 3.3	0.960
Health-related quality of life[4]				
Physical functioning, mean (SD)	64.02 ± 29.9	67.10 ± 26.1	66.54 ± 26.8	0.307
Social functioning, mean (SD)	79.25 ± 24.1	84.73 ± 22.6	83.74 ± 23.0	**0.033***
Role physical functioning, mean (SD)	52.84 ± 44.2	47.77 ± 43.3	48.69 ± 43.5	0.300
Role emotional functioning, mean (SD)	67.01 ± 40.4	67.58 ± 39.2	67.48 ± 39.4	0.898
Mental health, mean (SD)	74.19 ± 20.2	79.83 ± 17.8	78.80 ± 18.4	**0.006***
Vitality, mean (SD)	57.16 ± 25.8	60.14 ± 25.2	59.60 ± 25.3	0.295
Bodily pain, mean (SD)	74.39 ± 29.3	79.17 ± 24.9	78.30 ± 25.8	0.099
General health, mean (SD)	59.65 ± 24.7	58.61 ± 24.3	58.80 ± 24.3	0.704

*$P < 0.05$.

concerns (34% vs 16%, $P = 0.001$) and anxiety (52% vs 34%, $P < 0.001$) were more prevalent in women than in men, and remained so when adjusting for age, partner, time since first implantation, coronary artery disease etiology, symptomatic HF, comorbidity, device-related complications, and one or more shocks (≥1) (see Table II). There were no gender differences on depression

Table II.

Independent Associates of Anxiety, Depression, ICD Concerns, and Device Acceptance

	Anxiety OR (95% CI)	Depression OR (95% CI)	ICD Concerns OR (95% CI)	Device acceptance OR (95% CI)
Female gender	**2.60 (1.46–4.64)****	1.09 (0.48–2.46)	**1.81 (1.09–3.00)***	1.01 (0.56–1.78)
Older age	0.99 (0.97–1.01)	1.03 (1.00–1.05)	**0.98 (0.96–1.00)***	**1.02 (1.00–1.04)***
Cohabiting	1.16 (0.65–2.08)	0.87 (0.43–1.75)	0.76 (0.48–1.21)	**0.56 (0.35–0.92)***
Nonischemic etiology	1.55 (0.89–2.72)	1.44 (0.74–2.78)	1.17 (0.74–1.85)	1.24 (0.76–2.01)
Symtomatic HF	**6.23 (3.68–10.55)****	**9.07 (4.95–16.59)****	**3.96 (2.52–6.25)****	**6.75 (4.26–10.69)****
Complications	0.92 (0.38–2.24)	0.54 (0.17–1.78)	1.13 (0.55–2.34)	1.06 (0.48–2.35)
Time since first implant	1.01 (0.93–1.10)	1.00 (0.90–1.10)	0.96 (0.89–1.02)	0.95 (0.88–1.02)
Shocks	**2.02 (1.20–3.42)****	1.51 (0.80–2.87)	**2.70 (1.76–4.16)****	1.40 (0.89–2.21)
Comorbidity	0.99 (0.56–1.75)	0.66 (0.32–1.36)	1.05 (0.65–1.70)	0.98 (0.59–1.62)

*$P < 0.05$; **$P < 0.01$.

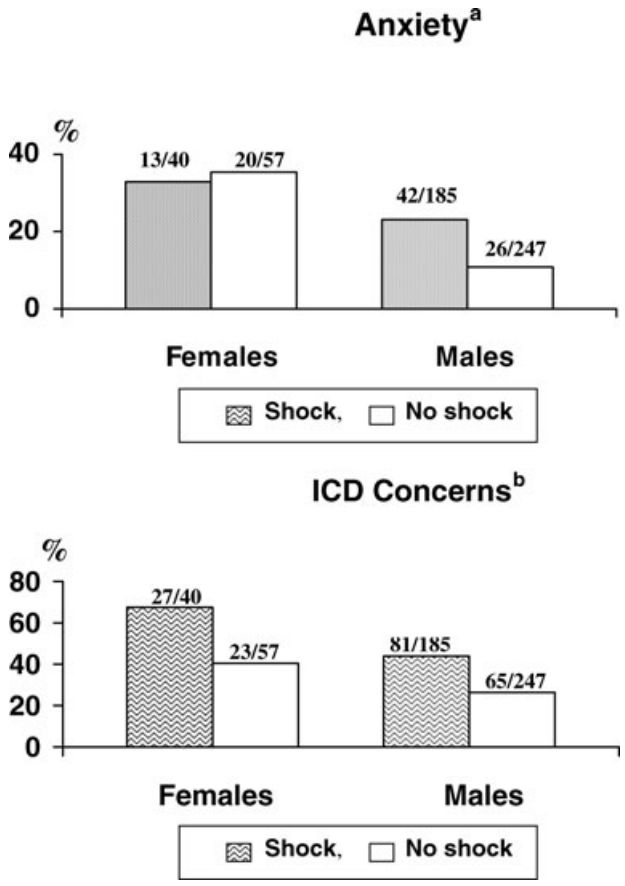

Figure 1. *Prevalence of anxiety and ICD concerns stratified by gender and shocks.* [a] *A cutoff of ≥8 on the HADS anxiety subscale was used to indicate clinically significant levels of anxiety.*[27] [b] *Scores on the ICDC-8 were dichotomized using the highest tertile to indicate a high level of device-related concerns (i.e., ICDC > = 74).*[34]

and device acceptance (see Table I), nor on the device acceptance subscales return to function, device-related distress, positive appraisal, and body image concerns (results not shown). Table II presents the independent associates of the psychological endpoints: anxiety, depression, device concerns, and device acceptance. Of note, symptomatic HF was associated with all psychological endpoints, whereas having experienced shocks was only associated with anxiety and ICD concerns.

Given that statistically significant differences were found between women and men on anxiety and ICD concerns, we further examined whether these differences were associated with shocks. A two-factor ANOVA using gender and shocks as fixed factors only found a main effect for gender on anxiety ($F_1 = 18.29$, $P < 0.001$), although there was a trend for the interaction effect gender by shocks ($F_1 = 3.20$, $P = 0.074$). For ICD concerns there was a significant main effect for both gender ($F_1 = 16.66$, $P < 0.001$) and shocks ($F_1 = 25.66$, $P < 0.001$) whereas the interaction effect gender by shocks failed to reach significance. This indicates that females experience high levels of anxiety regardless of shocks, whereas gender differences on ICD concerns are determined by both gender and shocks, with females having experienced shocks reporting the highest level of device-related concerns (see Fig. 1).

Gender Differences on HRQL

MANOVA showed women to have impaired HRQL on the social functioning and mental health subscales of the SF-36 (see Table I). When adjusting for age, partner, time since first implant, coronary artery disease etiology, symptomatic HF, comorbidity, device-related complications, and shocks (≥1), female gender was associated with impaired HRQL on the physical functioning, the social functioning, and the mental health subscales (see Table III). Table III presents all independent associates of HRQL. Of note, symptomatic HF was associated with impaired HRQL on all subscales, whereas shocks were not associated with any of the HRQL subscales.

Discussion

The results of the current study showed that female patients with an ICD were more likely to be anxious, and report high levels of ICD concerns and impaired HRQL on the mental health, physical, and social functioning subscales of the SF-36 than male patients. No statistically significant differences were found between women and men on depression and device acceptance. In adjusted analysis, symptomatic HF was generally associated with worse patient-centered outcomes, including more anxiety, depression, and ICD concerns, poor device acceptance, and impaired HRQL irrespective of gender. Furthermore, having received one or more shocks was another significant associate of increased anxiety and ICD concerns. Additional analyses examining the impact of both gender and shocks showed that female patients had the highest prevalence of anxiety irrespective of shocks, whereas females having experienced shocks showed the highest prevalence of ICD concerns.

Bilge and colleagues also found female gender to be associated with increased anxiety and depression,[17] whereas three other studies found no gender differences on anxiety or depression.[15,16,35] Examining device-related fears,

Table III.

Independent Associates of Health-Related Quality of Life[a]

SF-36 Subscales	PF $F_{1,512}$	SF $F_{1,512}$	RP $F_{1,512}$	RE $F_{1,512}$	MH $F_{1,512}$	VT $F_{1,512}$	BP $F_{1,512}$	GH $F_{1,512}$
Female gender	**5.22***	4.16*	0.02	0.82	**6.74***	2.08	1.30	0.01
Older age	**68.91****	0.84	**37.02****	**5.78***	0.05	2.46	**12.78****	2.05
Cohabiting	**4.58***	1.00	1.92	2.29	0.03	0.53	0.11	0.00
Nonischemic etiology	0.31	0.04	0.02	4.21*	0.42	0.43	**5.97***	1.37
Symptomatic HF	**248.76****	**234.53****	**111.34****	**84.46****	**109.86****	**212.45****	**129.65****	**175.69****
Complications	1.06	0.26	**4.15***	3.95*	0.02	3.48	0,00	0,05
Time since first implant	1.51	4.93*	3.23	1.57	1.60	**4.38***	0.16	0.13
Shocks	1.12	0.53	0.54	0.05	3.76	1.16	1.01	0.42
Comorbidity	**11.10****	**5.43***	1.20	0.04	0.18	0.87	**20.00****	**10.32****

*$P < 0.05$; **$P < 0.01$.
[a]SF-36: PF = physical functioning; SF = social functioning; RP = role physical functioning; RE = role emotional functioning; MH = mental health; VT = vitality; BP = bodily pain; GH = general health.

Sowell and colleagues found that female ICD patients reported more shock and death anxiety than men.[36] However, only one of these studies had a relatively large sample size (n = 180),[16] suggesting that the majority of studies may not have been sufficiently powered to adequately detect gender differences if present. In the current study, the sample size was large, and therefore, we were able to adjust for several potential confounding variables that may be associated with the patient-centered outcomes examined. The choice of self-report measure may be another reason for the inconsistent results. Two studies used HADS as a measure of anxiety and depression, but found inconsistent results,[17,35] whereas the two studies using the Beck Depression Inventory and Spielberger's State and Trait Anxiety Inventory found no differences.[15,16]

The current study extends previous research by examining gender differences on the disease-specific measures ICD concerns and device acceptance. Based on the literature, (i.e., Walker et al.[14]), we expected gender differences with regard to device acceptance, especially on the subscale of body image concerns; however, such differences could not be detected in the current sample. Reasons for this are unknown; however, a recent study of female ICD patients showed younger age to be associated with more shock anxiety, death anxiety, and body image concerns.[37] In the current study, male ICD patients had concerns about their body image on par with women; however, older age showed a small yet significant association with device acceptance in general, indicating that this association is not gender- but age-specific. Another reason could be that gender differences in concerns were more readily reported as general concerns about the ICD, since the current study showed women to be more likely to display high levels of ICD concerns. Of note, a previous study showed high levels of ICD concerns to be associated with increased anxiety and depression,[29,34] but although women experienced more anxiety and ICD concerns, they reported accepting their device on par with men. This is somewhat surprising, since a previous study showed increased anxiety and depression to be associated with less acceptance in a sample of both genders.[38] Taken together, this indicates that further studies are warranted that examine the influence of gender and age on psychological distress, ICD concerns, and device acceptance, including analyses that are stratified by gender.

Having experienced a shock was independently associated with both anxiety and ICD concerns. From a clinical point of view, this suggests that it is important to screen for and address ICD concerns and anxiety in those ICD patients whose device have fired, in order to prevent the negative impact of this experience. Furthermore, anxiety has been shown to precipitate arrhythmic events, making detection of increased anxiety an important issue in ICD patients.[39] The importance of this may be even more relevant in women than men, since both female gender and shocks were independently associated with anxiety and ICD concerns. Taken together, since women are generally known to report more anxiety than men, this may predispose them to experience more anxiety after ICD implantation, with ICD shocks possibly

accentuating anxiety by increasing levels of ICD concerns.

Our findings show that women experience impaired physical and social functioning compared to men. In addition, women experienced impaired HRQL on the mental health domain, which is consistent with the fact that women in general are more prone to experiencing anxiety and depression than men.[13,14] Although previous research has shown lower functional status in female ICD recipients,[16] this study did not use the SF-36, and the current results are not consistent with previous findings using the SF-36 showing better general health in female ICD recipients.[18] In sum, differences in research design (retrospective vs prospective), HRQL measure, sample size, and the lack of control for demographic and clinical variables in previous studies may account for some of these inconsistencies.

Taken together, the current study suggests that although psychosocial interventions targeting anxiety, ICD concerns, and HRQL are important to all ICD patients, women may have different needs compared to men following ICD implantation. Therefore, stratifying ICD rehabilitation by gender after implantation and especially after experiencing shocks may assist in targeting the specific needs of female ICD patients. A recent study of female ICD patients showed that younger age was associated with more shock anxiety, death anxiety, and body image concerns. In a recent review on psychological interventions following ICD implantation, almost all trials showed significantly reduced anxiety following intervention,[40] suggesting that such interventions may be beneficial to the anxious and concerned ICD patients.

The results of the current study should be interpreted with some caution. First, the cross-sectional design does not allow for the inference of cause and effect. Second, information on anxiety and depression were obtained by self-report rather than diagnostic interview, although all questionnaires were standardized and validated. Third, some clinical variables were obtained by self-report, which may have resulted in bias (i.e., willingness to report, retrieval bias, etc.). Fourth, data may not have been missing at random; hence, the assumptions for the imputation of missing data may have been violated.

This study also has several strengths, including the use of disease-specific questionnaires (i.e., the ICDC and the FPAS), the relatively high response rate, and the large sample size, which enabled us to address the issue of gender differences adequately.

In conclusion, in the current study female ICD patients were more likely to experience anxiety, high levels of ICD concerns, and impaired HRQL compared to males, whereas no differences were found on device acceptance and depression. The risk of increased anxiety and ICD concerns was especially salient in female ICD patients who were also shocked by the ICD. In clinical practice, female ICD patients should be closely monitored, and if warranted offered psychosocial intervention to avoid increasing the risk of arrhythmic events associated with increased anxiety.[39] Further studies are warranted to examine gender differences on psychological distress, ICD concerns, and device acceptance, as inconsistent findings in the literature may be attributable to methodological issues, including insufficient power to reliably address gender differences.

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